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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Robert McMeeking, Ph.D. Doc. 7314. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. IVC filters, such as Bard's Simon Nitinol Filter ("SNF"), originally were designed to be implanted permanently. Because some patients need only temporary filters, however, medical device manufacturers such as Bard developed retrievable filters.

Bard retrievable filters are spider-shaped devices with multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with hooks that attach to the IVC wall, and shorter curved arms that serve to catch or break up blood clots. Seven different

versions of Bard filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. Each of these filters is a variation of its predecessor. Bard first obtained Food and Drug Administration ("FDA") clearance to market the Recovery in 2003. The last-generation Denali received FDA clearance in 2013.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injury or death. Plaintiffs, among other things, allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that Bard filters are not defective and their overall complication rates are comparable to those of other IVC filters.

Plaintiffs have identified Dr. McMeeking, a mechanical engineer and materials scientist, as an expert witness on the design of Bard filters. Dr. McMeeking received his master's and doctorate degrees from Brown University. He currently teaches at the University of California, Santa Barbara, as a distinguished professor of structural materials and mechanical engineering, and has taught in these fields for more than 40 years. He is a member of prestigious engineering societies, has published peer-reviewed articles and served as an editor for engineering journals, and has received awards and honors for his work in the field of mechanical engineering. With respect to medical devices, Dr. McMeeking has testified before the FDA on device design and testing issues, and has served as a consultant to leading manufacturers of medical implants. Doc. 7318 at 3, 125-63.[1]

Dr. McMeeking has authored a report assessing design aspects of Bard filters. *Id.* at 1-175. The report provides Dr. McMeeking's credentials and a description of the methodology he employed, and sets forth objective industry and engineering standards

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

for the design of medical implants. *Id.* at 3-10. The report contains a preliminary description of each Bard filter (*id.* at 10-28), and a more detailed assessment of the design, mechanical behavior, and stress and strain characteristics of the Recovery and G2 (*id.* at 28-83). The detailed assessment includes, among other things, a discussion of Bard's *in vivo* loading and finite element analyses, its testing protocols, expected filter strains and their effects on reliability, the impact of device geometry and fabrication, and the risk of filter fracture, migration, perforation, and tilt. The report concludes with a list of documents reviewed, references, and figures and diagrams. *Id.* at 81-124.

Defendants do not challenge Dr. McMeeking's qualifications to opine about design aspects of Bard filters from an engineering perspective, nor do they seek to exclude his opinions that the filters are defective in various ways. Rather, Defendants ask the Court to exclude several categories of opinions: (1) Bard did not go far enough to reduce filter risks; (2) Bard failed to fully communicate relevant information to the FDA; (3) the complication rates for Bard retrievable filters are "dangerous"; and (4) the SNF is a safer, alternative device. Doc. 7314 at 2. The Court will address each category.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

III. Discussion.

A. Bard Did Not Go Far Enough to Reduce Filter Risks.

Defendants ask the Court to exclude Dr. McMeeking's opinion that Bard failed to "eliminate risks as far as reasonably practicable through inherently safe design and manufacture[.]" Doc. 7318 at 7. In support of this argument, however, Defendants do not cite to Dr. McMeeking's 82-page, single-spaced report, nor to his 16-page rebuttal report. *See* Docs. 7318, 7318-4. Defendants instead cite only to his deposition, to show both that he holds the opinion Defendants seek to exclude and that he lacks a reliable basis for it. Doc. 7314 at 4-7. Reading the motion provides the Court with no indication of what portions of Dr. McMeeking's lengthy report or rebuttal report Defendants seek to exclude. And Defendants' reply provides no additional help – it contains three pages of block quotes from Dr. McMeeking's deposition and not one citation to his reports. Doc. 8227 at 2-6.

Unfortunately, Plaintiffs' response is not much help either. Plaintiffs accuse Defendants of "cherry pick[ing]" language from Dr. McMeeking's deposition testimony, but they do not state whether they plan to present the specific opinion Defendants identify from the deposition, nor do they reveal its location in his report or the complete basis for it. Doc. 7806 at 8-10. Plaintiffs do assert that the report identifies proposed design changes Bard could have made, but they cite only two examples: eliminating strain concentration and fretting of limbs. *Id.* at 7. Plaintiffs also note that Dr. McMeeking found Bard's design process to be deficient because they did not duplicate past failures or consider worst-case scenarios. *Id.* at 7. Plaintiffs contend generally that his opinions are reliable because they are based on his quantitative and finite element analyses, mathematical calculations, and a review of Bard's testing data and other engineering documents. *Id.* at 6, 11.

Having read the briefs, more than once, the Court cannot determine precisely what opinions in the reports Defendants seek to exclude, whether Plaintiffs even intend to present the opinion Defendants cite from the deposition, and, if so, where that opinion is

supported in the reports. The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony admissible, but Defendants have the burden of at least identifying the opinions Plaintiffs must defend in a *Daubert* motion. Given the state of the parties' briefing, the Court cannot conclude that portions of the planned McMeeking testimony should be excluded.

Dr. McMeeking's report does identify the following general principle for the safety and performance of medical devices:

> The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; *eliminate risks as far as reasonably practicable through inherently safe design and manufacture*; reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and inform users of any residual risks.

Doc. 7318 at 7 (emphasis added). Elsewhere in his report, Dr. McMeeking states that Bard failed to apply this and other standards, grouping all of the violated standards together in a single sentence. *Id.* at 12, 17, 22, 27. Each of these statements is made in the context of Dr. McMeeking's discussion of a specific generation of Bard IVC filters and its defects. The Court cannot tell what exactly Plaintiffs intend to elicit on this subject at trial, and the parties' briefs largely fail to discuss the statements in their contexts in the report. Objections will have to be resolved at trial.

Dr. McMeeking's report does identify certain alleged design defects, including strain concentrations causing rapid limb fatigue and fracture, the unstable manner in which the filter head holds the limbs in place, the instability of the filter in the IVC leading to tilt and perforation, and the small diameter of the filter limbs causing perforation. Doc. 7318 at 11-12. These alleged defects lead Dr. McMeeking to conclude that the G2 was not thoroughly tested, that attempts to identify all possible failure modes

were inadequate, and that Bard did not use strain-analytical methods. *Id.* Some of these opinions are close to the opinion Defendants seek to exclude, but Defendants say nothing about the reasoning provided for these opinions in Dr. McMeeking's report, and the Court cannot conclude from somewhat unconnected deposition answers that they should be excluded. Again, the Court will rule on specific objections at trial.

B. Bard Failed to Fully Communicate Relevant Information to the FDA.

Dr. McMeeking states in his report that Bard was not "frank and honest" with the FDA in that the company "did not fully inform the FDA of deficiencies that the G2 filter was exhibiting after implant." Doc. 7318 at 12, 18. He clarified during his deposition that while he is not offering an opinion as to whether Bard's corporate behavior met the FDA's expectations, "in a couple of situations, [he] identified information that Bard gave to the FDA which was not correct[.]" Doc. 7318 at 17-18.

Defendants concede that Dr. McMeeking is qualified to opine that certain Bard documents provided to the FDA contain technical inaccuracies. Docs. 7314 at 7, 8227 at 7. They argue, however, that the opinion that Bard was not "frank and honest" with the FDA should be excluded because Dr. McMeeking is not qualified to offer the opinion and has identified no reliable methodology. Doc. 7314 at 7-8. The Court agrees.

Dr. McMeeking has testified before the FDA based on his knowledge and experience as a mechanical engineer and materials scientist (Doc. 7318 at 3), but this does not make him an FDA regulatory expert. He has identified no other expertise or specialized knowledge that enables him to opine on what the FDA requires of IVC filter manufacturers. And he does not purport to know the full context and content of Bard's communications with the FDA, or the company's intent behind any communication.

Plaintiffs note that Dr. McMeeking relies on the opinions of Dr. Parisian, and contend that an expert's opinions may be based on the reliable opinions of other experts. Doc. 7806 at 12-13. But Dr. McMeeking cannot merely act as a conduit for Dr. Parisian's opinions regarding Bard's communications with the FDA. *See* Doc. 9771 at 5; *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods.*

Liab. Litig., 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013). His report and testimony suggest he is doing just that. He states that Bard's failure to be "frank and honest" with the FDA "[has] been documented by Parisian, where further details are to be found." Docs. 7318 at 12. And when asked about the opinion during his deposition, he stated: "The basis, I'm relying on Dr. Parisian for that opinion." 7318-1 at 17. As the Court previously has held, an expert cannot simply repeat the opinions of other experts as his own when he has done nothing to verify the accuracy of the opinions. Doc. 9772 at 5; *see In re Matter of Complaint of Ingram Barge Co.*, 2016 WL 4366509, at *4 (N.D. Ill. Aug. 16, 2016) ("[The expert's] opinions . . . do not rely 'in part' on the purported expertise of other testifying experts. Rather, [the expert] repeats and concurs with their opinions, without additional analysis. The Court does not need an expert to reiterate other experts' testimony.").

The Court will exclude Dr. McMeeking's opinion that Bard was not "frank and honest" with the FDA. Dr. McMeeking may, however, opine from an engineering perspective that certain information Bard provided to the FDA is not correct.

C. Filter Complication Rates Are Dangerous.

Dr. McMeeking states in his report that he has reviewed Dr. Betensky's analysis of adverse event reporting and finds the analysis to be consistent with and supportive of his engineering-based opinions. Doc. 7318 at 27-28. Dr. McMeeking stated during his deposition that he will offer no opinion on the relative rates of filter complications. Doc. 7318-1 at 29. When asked about opinions regarding the medical literature, he stated:

> I'm not going to give opinions on what's in the medical literature, other than to say that they're consistent with my assessment of the engineering considerations of the filter *and that they tend to confirm that the filters . . . are dangerous*.

Id. at 30 (emphasis added). Defendants note that it is unclear whether Dr. McMeeking intends to offer opinions about "dangerous" complication rates, and they seek a ruling from the Court excluding any such opinion. Doc. 7314 at 9-11 & n.2.

Plaintiffs make clear in their response that Dr. McMeeking will offer no such opinion and that he relies on Dr. Betensky's report only to confirm the results of his own engineering analysis. Doc. 7806 at 14. The Court will accept this representation by Plaintiffs. Defendants may object if they believe Dr. McMeeking is rendering an opinion that Bard filters are dangerous.

D. The SNF is a Safer Alternative Filter.

Dr. McMeeking prepared a rebuttal report to several of Defendants' experts. Doc. 7318-4. He concludes the report as follows:

> Given my analysis as detailed above, I conclude from an engineering perspective that the design of the SNF is substantially better than those of the Recovery, G2 and similar Bard filters, with respect to migration, tilt, arm fracture and arm perforation, after considering the combination of attributes that are positive or negative in each case for each filter design. Therefore, based on my assessments it is my opinion that, in sum, the SNF is a safer filter than the Recovery, G2, and similar Bard filters.

Id. at 17.

Defendants contend that Dr. McMeeking should not be allowed to make the leap from evaluating the design characteristics of Bard filters to opining that the SNF is a safer device. Doc. 7314 at 12. Defendants cite cases applying a specific requirement of New York law – that a plaintiff in a design defect case prove the product was "not reasonably safe because there was a substantial likelihood of harm and *it was feasible to design the product in a safer manner*." *Voss v. Black & Decker Mfg. Co*., 450 N.E.2d 204, 208 (N.Y. 1983) (emphasis added). Defendants' cited cases, *McCarthy v. Olin Corp.*, 119 F.3d 148 (2d Cir. 1997), and *Felix v. Akzo Nobel Coatings*, 262 A.D.2d 447 (N.Y. App. Div. 1999), held that the allegedly dangerous feature of the challenged product was in fact necessary to make the product function as intended, and that it was therefore not feasible to design the product in a safer manner. In *McCarthy*, the alleged defect – the expansion upon impact of hollow-point bullets – was an intentional element of the product's design. The court noted that "the very purpose of [hollow-point] bullets is to kill or cause severe wounding," and the bullets "performed precisely as intended[.]"

119 F.3d at 155. In *Felix*, the plaintiff's own expert admitted that the very nature of the quick-drying lacquer product "necessitated that it contain a highly flammable solvent," and that "nothing [could] be introduced to the formula to make it safer without creating an entirely different product." 262 A.D.2d at 448.

Defendants make no effort to show that the law governing the bellwether trials will impose the same requirement as New York law. Nor do they address whether the functional differences between the SNF and the retrievable filters in this case are so great that the retrievable filters could not feasibly be designed liked the SNF. (That may well be a subject for expert testimony, if such testimony has been disclosed.) As a result, the Court cannot conclude that Dr. McMeeking's safety comparison will be inadmissible in the bellwether trials.

In their reply brief, Defendants cite one case that applies Georgia law – the law to be applied in the first bellwether trial – but they do not discuss the case or Georgia law. Doc. 8227 at 11 (citing *Mascarenas v. Cooper Tire & Rubber Co*., 643 F. Supp. 2d 1363, 1369 (S.D. Ga. 2009)). The case notes that Georgia applies a risk-utility analysis to design defect claims. The essential inquiry "is whether the design chosen was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware." *Mascarenas*, 643 F. Supp. 2d at 1369 (quotation marks and citation omitted). Among a number of factors to be considered are "the state of the art at the time the product is manufactured" and "the ability to eliminate danger without impairing the usefulness of the product or making it too expensive." *Id.* "In general, weighing the risk-utility factors is a task left to the jury." *Id.* The Court cannot conclude from this law that Dr. McMeeking's opinion will be inadmissible in the first bellwether trial, particularly in the absence of arguments from the parties. His opinion that the SNF is safer may well be one factor for the jury to consider, along with Defendants' arguments that retrievable filters are functionally different from the SNF and therefore could not feasibly have been designed in the same way.

Defendants argue that Dr. McMeeking is not qualified to opine that the SNF would have been a safer alternative filter for any particular plaintiff, including the plaintiffs in the bellwether cases. Doc. 7314 at 13. Plaintiffs agree, and have made clear that Dr. McMeeking will offer no such opinion at trial. Doc. 7806 at 21.

Finally, Defendants object to Dr. McMeeking relying on Dr. Betensky's opinions that the SNF is a safer device. Doc. 7314 at 12. Contrary to Defendants' assertion, however, Dr. McMeeking's methodology is not mere "blind reliance" on Dr. Betensky's work. Doc. 8227 at 14. His opinion is based largely on his own independent engineering assessment of the SNF and the G2 and Recovery filters. Doc. 7318-4 at 9-17. He notes that his comparison of the filters "is in agreement with the adverse event reports." *Id.* at 9. That is not an improper adoption of Betensky's work.

The Court will not grant Defendants' request to preclude Dr. McMeeking from opining that the SNF is a safer device than Bard retrievable filters. But he may not opine that the SNF would have been a safer alternative for any particular plaintiff.[2]

IT IS ORDERED that Defendants' motion to exclude the opinions of Robert McMeeking, Ph.D. (Doc. 7314) is **granted in part** as set forth in this order.

Dated this 8th day of February, 2018.

David G. Campbell
United States District Judge

[2] Defendants also argue generally that the opinions of Dr. McMeeking challenged in their motion will not assist the jury, but they provide no explanation for this assertion. Doc. 7314 at 3.